EXHIBIT 52

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

EXCESSIVE MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS

JUNE GIBBS BROWN
Inspector General

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OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter or many prescription drugs that are self-administered. However, the program does pay for certain categories of drugs used by Medicare beneficiaries.

On January 1, 1998, Medicare Part B will begin to reimburse covered drugs at 95 percent of the average wholesale price. Currently, Medicare carriers may determine the amounts that Medicare will pay for these drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is reported in *The Red Book* and other pricing publications and databases used by the pharmaceutical industry. Historically, it has been the AWP that carriers have used to develop Medicare reimbursement for prescription drugs.

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on 22 drug codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

FINDINGS

Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996.

Medicare and its beneficiaries payments for the 22 drugs would have been reduced by an estimated 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP's were the basis for Medicare reimbursement. Similar savings of $445 million were also identified for 1995. If the savings percentage for just the 22 drugs was applied to Medicare's allowances for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. Medicare allowed at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed amounts were more than the actual average wholesale price in both 1995 and 1996. Not only did Medicare pay more than the actual average wholesale price, the program allowed more than the highest average wholesale price for every drug.

There is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. **We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.** Beginning in January 1998, Medicare reimbursement for prescription drugs will be 95 percent of average wholesale price. We believe that the 5 percent reduction is not a large enough decrease and that further options to reduce reimbursement should be considered.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier the providers bill. **We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.** The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all

necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

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PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare Coverage and Payment for Prescription Drugs

While Medicare does not pay for over-the-counter or many prescription drugs that are self-administered, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare will cover certain drugs used in association with dialysis or organ transplantation. Drugs used for chemotherapy and pain management in cancer treatments are also covered. The program also covers certain types of vaccines such as those for flu and hepatitis B.

Depending on the type of drug, both local carriers and four Durable Medical Equipment Regional Carriers (DMERCs) are responsible for processing claims for drugs covered under Part B of the Medicare program. The carriers are responsible for determining the allowance that Medicare will pay for these drugs.

Carriers base their current allowance rates on the regulations established in 42 Code of Federal Regulation 405.517. According to the regulations, Medicare computes an allowed amount for drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar pricing publications and databases used by the pharmaceutical industry. The AWPs are mainly provided to these sources by pharmaceutical manufacturers. If a drug has multiple sources (more than one brand or generic version), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. Historically, carriers have utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs.

Drugs are billed to the Medicare program based on codes developed by the Health Care Financing Administration (HCFA). These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand

or generic version of the drug was administered; nor do the codes provide information on the manufacturer or distributor of the drug provided.

Change in Medicare Reimbursement for Prescription Drugs

In recent legislation, Congress established reimbursement for prescription drugs at 95 percent of a drug's average wholesale price. This change will be implemented on January 1, 1998.

A different proposal to change the Medicare reimbursement methodology for prescription drugs was included in the President's FY 1998 budget. The proposal provided for the amendment of 42 U.S.C. 1395u(o) to set payment for drugs not otherwise paid on a cost or prospective payment basis. The revision set payment at the lowest of: actual acquisition cost to the provider, AWP, median actual acquisition cost, or an amount otherwise determined under the Code. The actual acquisition cost was defined to include all discounts, rebates, or any other benefit in cash or in kind. This proposal was supported by HCFA but was not the version eventually adopted by Congress.

Related Work by the Office of Inspector General

This report is one of several Office of Inspector General reports concerning Medicare payments for prescription drugs. In 1996, we released a report entitled *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-96-00420) which compared Medicare drug reimbursement mechanisms with Medicaid payment mechanisms for 17 drugs and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid. The OIG has also produced several reports focusing on inhalation drugs paid for by Medicare. In *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), we found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. In a companion report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many retail and mail-order pharmacies charge customers less for generic albuterol sulfate than Medicare's allowed price. *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393) found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs.

The Office of Inspector General also recently issued a report on acquisition costs of brand name drugs by Medicaid pharmacies. In *Medicaid Pharmacy - Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs* (A-06-96-00030), the Office of Audit Services estimated that the actual acquisition cost for brand name drugs was 18 percent below AWP.

METHODOLOGY

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on drug

codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

We collected from three sources the data needed to compare Medicare allowed amounts to actual wholesale prices. For information on Medicare allowances for prescription drugs, we compiled statistics from HCFA's National Claims History (NCH) File. We then collected Medicare reimbursement rates for specific drugs from contracted carriers. Lastly, we analyzed wholesale prices from drug wholesalers and group purchasing organizations.

Medicare Allowance Data for Prescription Drugs

We decided to review the 30 drug codes with the highest Medicare allowances for 1995. We chose 1995 since the Medicare claims data was 98 percent complete at the commencement of the inspection. To determine the Medicare allowances for prescription drugs in 1995, we compiled a list of HCPCS codes that represent all of the drugs which Medicare reimburses. The drug code list primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging, and immunization or vaccine codes that are represented by a five digit numeric code.

We then retrieved NCH allowance and utilization data using HCFA's Part B Extract and Summary System (BESS). We aggregated the allowances for each code to calculate Medicare's total prescription drug allowance for 1995. We then determined the 30 drug codes with the highest individual allowances for that year.

Using NCH data, we calculated the Medicare allowances for all drugs in 1996. We also determined the 1996 allowances for the 30 drug codes with the highest allowances in 1995. At the time of our inspection, the NCH data for 1996 was 95 percent complete.

Carrier Allowances for Prescription Drugs

We sent requests for carrier drug reimbursement rates to Medicare's 26 fraud information specialists. The fraud information specialists coordinate work among all HCFA contractors in the regions they represent. There are a total of 61 geographical regions that local carriers cover. We received drug allowances from 50 of the 61 areas. We also received responses from two of the four DMERCS.

We requested allowed amounts for prescription drug codes with the highest total allowances in 1995. The allowed amount reflects the dollar reimbursement that Medicare will allow for the specific dosage defined by the HCPCS drug code. We

asked the carriers to provide allowed amounts by quarter for calendar years 1995, 1996, and 1997. However, some carriers provided us with data on a yearly basis and others only for certain quarters.

Some carriers also furnished allowed amounts for both participating and non-participating physicians. Physicians participating in the Medicare program agree to accept Medicare allowed amounts as total reimbursement for their services. Participating physicians receive 5 percent more in Medicare reimbursement for services. In the instances where both participating and non-participating allowed amounts were provided, we used the participating physician allowed amounts. More than three-quarters of physicians across the nation now participate in the Medicare program.

Utilizing the data provided by carriers, we calculated an average Medicare allowed amount for each drug code by year. These allowed amounts were used to compare Medicare reimbursement with drug acquisition costs for physicians and suppliers.

Prescription Drug Costs for Physicians and Suppliers

In order to determine acquisition costs for the top drugs, we reviewed 1995 and 1996 prices offered by wholesale drug companies and group purchasing organizations (GPOs). We obtained pricing lists/catalogs for seven wholesale drug companies and seven group purchasing organizations. Group purchasing organizations provide members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or a drug wholesaler that agrees to accept the negotiated price. For the GPOs we reviewed, most of the major drug wholesalers accept the GPO contracted price.

The 14 pricing sources we used provided pharmaceutical products mainly to physician practices and specialized or closed pharmacies. Depending on individual State licensing practices, specialized or closed pharmacies normally do not provide retail prescription drug dispensing to walk-in customers. Instead, they often provide prescription drugs for home infusion or inhalation therapy.

After beginning our review of wholesale drug costs, we determined that 2 of the top 30 drugs codes we identified for 1995 could not be used for the inspection. Code J7699 represents not-otherwise-classified inhalation drugs and Code J7190 for Factor VIII (human anti-hemophilic factor) has a dosage requirement that is difficult to determine. Therefore, obtaining wholesale prices for these two codes would not be possible.

For the remaining 28 drug codes identified for our analysis, 17 were used for the treatment of cancer/leukemia, 5 were inhalation drugs, 2 were vaccines, and 2 were used for organ transplantation or valve replacement complications. There was also a drug used for immunodeficiencies and another for severe infections. The majority of

these drugs would most likely be purchased and administered by physicians or other health care practitioners. The inhalation drugs or drugs used for home infusion would most likely be provided by a specialized pharmacy or supplier.

For the 28 drug codes, we collected 1995 and 1996 prices from the 14 drug pricing lists/catalogs. We decided not to present prices for drugs where fewer than two different pricing sources could be identified per year. There were 6 codes that did not meet the two source minimum. These codes were: vaccine codes 90724 and 90732, inhalation codes J7645 and J7660, and codes K0121 and J1245 used for transplants/valve replacements. A list of the HCPCS codes' descriptions and dosages for the final 22 drugs used for our evaluation is provided in Appendix A.

The 22 drug codes represented 10 single-source, 9 multiple-source, and 3 multiple-brand drugs. A single-source drug has only one brand of drug available. A multiple-source drug has both brand and generic forms of the drug available. There were no drug products manufactured in the dosage defined by the HCPCS code for five drugs (J7620, Q0136, J2405, J9181, J9293). We selected all the drugs with higher dosages that met the drug description and applied a conversion factor to achieve prices for the HCPCS-specified dosage. For an additional code (J1561), we found that out of the multitude of prices we could find for the drug only three met the exact dosage requirement. Since the higher dosage products seemed to be the more prevalent way of purchasing this drug, we included them in our analysis.

We searched the 14 price lists for both brand and generic prices during 1995 and 1996. For nine drug codes, we obtained between 5 and 8 separate prices. Eight of the nine were single-source drugs. For another eight codes, we found between 12 and 29 separate prices. We found between 30 and 70 separate prices for the remaining five drug codes.

Calculation of Potential Medicare Savings for Prescription Drugs

To determine the potential savings to Medicare if acquisition costs rather than published AWPs were used for reimbursement, we compared Medicare's allowed amounts to the wholesale prices we collected. To do this, we compiled all the pricing information from the sources reviewed and calculated an average price by year for all 22 codes. We believe that the pricing information supplied by the drug wholesalers and group purchasing organizations provides factual evidence of acquisition costs available to physicians and suppliers.

The average price or average acquisition cost for each drug code was then compared to the average Medicare allowed amount that we calculated from the carrier data. For each drug code, the difference between the average price and the Medicare allowed amount was computed. We then applied this amount to the number of services paid by Medicare for each drug in 1995 and 1996. The resulting dollar amounts were aggregated to determine the total estimated savings to Medicare if acquisition costs rather than AWP had been used to determine reimbursement.

Appendix B provides the average Medicare allowed amounts and actual average wholesale prices computed for the 22 drug codes reviewed. Although we utilized the actual average wholesale price to report savings in the findings section of this report, the appendices also contains the potential savings to Medicare if the lowest and highest wholesale prices found were compared to the Medicare allowed amount.

FINDINGS

MEDICARE ALLOWANCES FOR 22 DRUGS EXCEEDED ACTUAL WHOLESALE PRICES BY $447 MILLION IN 1996.

Medicare carriers now base prescription drug reimbursement on published average wholesales price of drugs. However, physicians and suppliers are often able to purchase drugs for prices that are much lower than the official AWPs provided by manufacturers.

After reviewing wholesale drug catalogs and group purchasing organizations' prices for the 22 drugs, we estimated that $447 million would have been saved by Medicare and its beneficiaries if Medicare had based reimbursement on actual wholesale prices rather than published AWPs in 1996. These wholesale prices are available to physicians, specialized pharmacies, and other suppliers. These wholesale prices represent the actual acquisition costs to physicians and suppliers that bill Medicare for these drugs.

Total allowed charges for the 22 drugs would have been reduced by 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP were the basis for Medicare reimbursement. The 22 drugs represented 67 percent of the $2.3 billion in total Medicare drug allowances for 1996. If the savings percentage for just the 22 drugs was applied to Medicare's reimbursement for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

The savings for individual drugs ranged from 13 percent of allowances for three drugs (J9202, Q0136, J9185) to a high of 92 percent for leucovorin calcium (J0640). Almost half of the drugs (10 of 22) had estimated savings greater than 40 percent of allowances. A table provided in Appendix C lists the 1996 allowances and estimated savings for the 22 drugs. The table also lists the percentage of allowance saved for each individual drug if reimbursement had been based on the actual average wholesale prices available for the drug.

Similar savings of $445 million were identified for 1995.

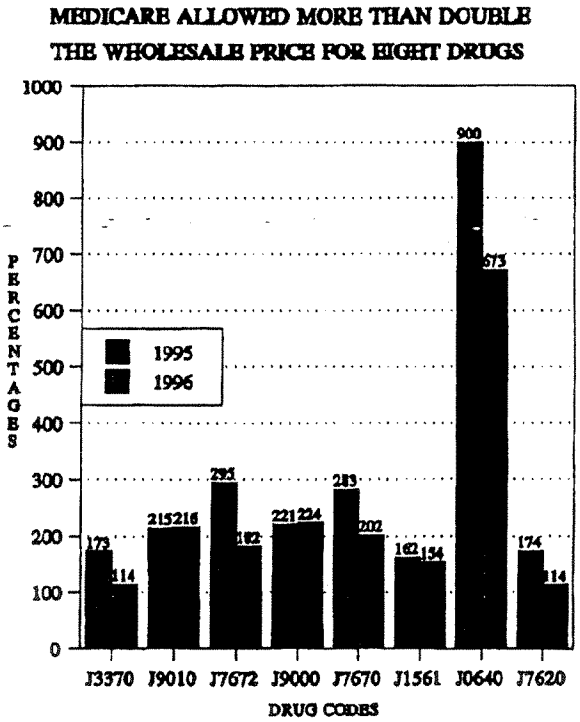
If Medicare had based reimbursement on actual wholesale costs in 1995, the program and its beneficiaries would have saved an estimated 35 percent in payments for the 22 drugs. This would have amounted to savings of $445 million on $1.3 billion in total 1995 program expenditures for these drugs. The $1.3 billion in expenditures for the 22 drugs represented 70 percent of the $1.8 billion in Medicare total drug allowances for 1995.

The percentage of allowance saved for individual drugs ranged from 15 percent for carboplatin (J9405) and fludarabine phosphate (J9185) to 95 percent for leucovorin calcium (J0640). Half of the drugs (11 of 22) had estimated savings greater than 40

percent of their 1995 allowances. Individual drug allowances and savings for 1995 are presented in Appendix C.

FOR MORE THAN ONE-THIRD OF THE 22 DRUGS REVIEWED, MEDICARE ALLOWED AMOUNTS WERE MORE THAN DOUBLE THE ACTUAL AVERAGE WHOLESALE PRICE AVAILABLE TO PHYSICIANS AND SUPPLIERS.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. For one drug, Medicare allowed 900 percent more than the average price available for the drug in 1995 and 673 percent more in 1996. The chart below provides the percentage of the Medicare allowed amount that is greater than the actual average wholesale price for each of the eight drugs.



Medicare allowances were also significantly higher than acquisition costs for the remaining 14 drugs reviewed. Medicare allowed 60 to 95 percent more than the actual average wholesale price for 3 drugs in 1995 and 2 drugs in 1996. Medicare allowed amounts were higher by 20 to 50 percent for 9 drugs in 1995 and 8 drugs in 1996. Reimbursement was between 11 and 18 percent more for the remaining 2 drugs in 1995 and 4 drugs in 1996.

Medicare and its beneficiaries paid at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed more than the average actual price in both 1995 and 1996. Not only did Medicare pay more than the average price, the program allowed more than even the highest wholesale price obtained for every drug. Appendix B provides information on the highest and lowest wholesale price available for each drug in 1995 and 1996.

Based on the differences found between Medicare allowed amounts and actual wholesale prices, it is apparent that the current Medicare reimbursement methodology is based on an significantly inflated AWP statistic which bears little resemblance to actual wholesale prices available in the marketplace.

THERE IS NO CONSISTENCY AMONG CARRIERS IN ESTABLISHING AND UPDATING MEDICARE DRUG REIMBURSEMENT AMOUNTS.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. A carrier reimbursed code J9217 (leuprolide acetate, a single-source drug) at $496.25 for all of 1995. Another carrier allowed $412.29 for the first quarter of 1995, $439.30 for the second and third quarters, and $477.50 for the fourth. For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State. The second carrier eventually paid $496.26 for this code in the first quarter of 1996. However, the first carrier increased reimbursement to $515.63 in the same quarter.

Little uniformity was found among carriers when comparing changes in reimbursement from the first quarter of 1995 to the second quarter of 1997. One carrier's reimbursement for code J9000 (doxorubicin hcl, 10 mg.) increased 128 percent from $20 to $45.50. Another carrier's rate for the same code decreased 19 percent from $48.20 to $39.10.

Since Medicare does not allow geographical differences to effect drug reimbursement, variations would seem to be caused by carriers' decisions regarding when to update reimbursement, what sources to use for documenting AWPs, and in the case of multiple-source drugs which generic drugs to include in calculating the median statistic.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physicians and suppliers that bill for these drugs. By basing reimbursement on published AWPs rather than more appropriate acquisition or wholesale prices, we estimate that Medicare and its beneficiaries paid nearly one billion dollars more for 22 drugs in 1995 and 1996.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. **We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.** The HCFA concurred with the recommendation. We urge readers to review our prior report, *Medicare Payments for Nebulizer Drugs*, which provided the full text of HCFA's comments on our recommendation.

For our readers' convenience, the options for changing Medicare's reimbursement methodology that appeared in the recommendation are presented below. We have modified the original discounted AWP and acquisition cost options in response to the evidence presented in this report concerning the large disparity between published AWPs and actual average wholesale prices available for prescription drugs.

Options for Changing Medicare's Reimbursement Methodology for Prescription Drugs

Discounted Wholesale Price

Beginning in January 1998, Medicare will reimburse prescription drugs at 95 percent of AWP. Many State Medicaid agencies use greater discounted AWPs to establish drug prices. Medicare could also base its drug payments on this larger discounted average wholesale prices. We believe that the 5 percent discount that will soon be implemented is not a large enough decrease. Upon implementation of this option, some type of general limit should be applied to the prices to ensure that inappropriate increases in average wholesale prices that could occur in subsequent years do not adversely affect Medicare payments. In addition, the Secretary should be granted the authority to conduct sample surveys of actual wholesale prices to determine the amount of difference between actual average wholesale prices and published AWPs. The percentage difference found in the sample could then be applied to all AWPs used by the program to determine drug reimbursement.

Acquisition Cost

Medicare could base the payment of drugs on either actual or estimated acquisition costs. Although Medicare currently has the authority to use EAC, carriers have yet to

successfully implement the option. Upon implementation of either the actual or estimated method, we believe that some type of general limit should be applied to ensure that inappropriate increases in drug prices do not occur in subsequent years.

Manufacturers' Rebates

Medicare could develop a legislative proposal to establish a mandated manufacturers' rebate program similar to Medicaid's rebate program. We recognize that HCFA does not have the authority to simply establish a mandated manufacturers' rebate program similar to the program used in Medicaid. Legislation was required to establish the Medicaid rebate program, and would also be required to establish a Medicare rebate program. We have not thoroughly assessed how a Medicare rebate program might operate, what administrative complexities it might pose, or how a Medicare rebate program might differ from a Medicaid rebate program. We believe, however, the legislative effort would be worthwhile. The same manufacturers that provide rebates to Medicaid make the drugs that are used by Medicare beneficiaries and paid for by the Medicare program.

To implement this option, HCFA would have to revise Medicare's claims coding system which does not identify the manufacturer or indicate if the drug is a brand name or a generic equivalent, information that is needed to discount the AWP and obtain a rebate for a specific drug. Medicaid uses National Drug Codes (NDC) in processing drug claims. The NDC identifies the manufacturer and reflects whether the drug is a brand name or a generic equivalent.

Competitive Bidding

Medicare could develop a legislative proposal to allow it to take advantage of its market position. While competitive bidding is not appropriate for every aspect of the Medicare program or in every geographic location, we believe that it can be effective in many instances, including the procurement of drugs. Medicare could ask pharmacies to compete for business to provide Medicare beneficiaries with prescription drugs. All types of pharmacies could compete for Medicare business, including independents, chains, and mail-order pharmacies.

Inherent Reasonableness

Since Medicare's guidelines for calculating reasonable charges for drugs result in excessive allowances, the Secretary can use her "inherent reasonableness" authority to set special reasonable charge limits. If this option is selected, however, it will not be effective unless the Secretary's authority to reduce inherently unreasonable payment levels is streamlined. The current inherent reasonableness process is resource intensive and time consuming, often taking two to four years to implement. Medicare faces substantial losses in potential savings--certainly in the millions of dollars--if reduced drug prices cannot be placed into effect quickly.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier providers bill. **We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCPCS drug code.** The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways. The full text of HCFA's comments are provided in Appendix D.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

APPENDIX A

Description of 22 HCPCS Codes

Code	Description
J9217	Leuprolide Acetate (for depot suspension), 7.5 mg.
J7620	Albuterol Sulfate, 0.083%, per ml., inhalation solution administered through DME
J9265	Paclitaxel, 30 mg.
J9202	Goserelin Acetate Implant, per 3.6 mg.
J0640	Injection, Leucovorin Calcium, per 50 mg.
J9045	Carboplatin, 50 mg.
J1440	Injection, Filgrastim (G-CSF), per 300 mcg.
Q0136	Injection, Epoetin Alpha, (For Non-ESRD Use), per 1000 units
J2405	Injection, Ondansetron Hydrochloride, per 1 mg.
J1625	Injection, Granisetron Hydrochloride, per 1 mg.
J1561	Injection, Immune Globulin, Intravenous, per 500 mg.
J7670	Metaproterenol Sulfate, 0.4%, per 2.5 ml., inhalation solution administered through DME
J1441	Injection, Filgrastim (G-CSF), per 480 mcg.
J9182	Etoposide, 100 mg.
J9000	Doxorubicin HCL, 10 mg.
J9031	BCG (Intravesical) per instillation
J9181	Etoposide, 10 mg.
J7672	Metaproterenol Sulfate, 0.6%, per 2.5 ml., inhalation solution administered through DME
J9293	Injection, Mitoxantrone Hydrochloride, per 5 mg.
J9185	Fludarabine Phosphate, 50 mg.
J9010	Doxorubicin HCL, 50 mg. (code discontinued 12/31/96)
J3370	Injection, Vancomycin HCL, up to 500 mg. (code discontinued for infusion 9/1/96)

APPENDIX B

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1995 AND 1996

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1995

HCPCS Code	Average Medicare Allowed Amount	Actual Average Wholesale Price	Savings Based on Actual Average Wholesale Price	Lowest Wholesale Price Found	Savings Based on Lowest Wholesale Price	Highest Wholesale Price Found	Savings Based on Highest Wholesale Price
J9217	$474.67	$394.33	$83,728,802	$391.00	$87,202,882	$396.00	$81,991,762
J7620	$0.42	$0.15	$106,352,439	$0.12	$119,040,331	$0.21	$85,081,951
J9265	$180.82	$148.70	$14,425,220	$146.10	$15,592,891	$150.00	$13,841,385
J9202	$353.82	$292.95	$11,716,412	$286.84	$12,891,775	$296.00	$11,128,731
J0640	$23.27	$2.33	$61,175,769	$1.89	$62,449,291	$2.90	$59,499,161
J9045	$78.01	$66.67	$7,226,520	$64.90	$8,352,014	$67.55	$6,663,773
J1440	$149.46	$124.47	$8,620,001	$124.20	$8,711,972	$125.00	$8,436,058
Q0136	$11.92	$9.92	$7,942,246	$8.84	$12,246,366	$10.70	$4,850,833
J2405	$5.65	$4.33	$10,591,319	$3.91	$14,012,161	$5.31	$2,712,031
J1625	$165.29	$123.58	$9,709,625	$117.00	$11,240,029	$132.80	$7,562,405
J1561	$42.21	$16.12	$23,339,871	$9.33	$29,422,374	$32.11	$9,036,521
J7670	$1.22	$0.32	$23,986,743	$0.26	$25,544,703	$0.40	$21,872,652
J1441	$234.96	$195.50	$5,256,151	$188.90	$6,135,284	$198.80	$4,816,584
J9182	$131.25	$76.70	$11,660,930	$56.00	$16,085,515	$113.55	$3,783,570
J9000	$42.14	$13.12	$11,445,719	$10.90	$12,319,556	$14.70	$10,821,019
J9031	$155.20	$120.54	$3,659,236	$94.28	$6,430,898	$138.44	$1,769,236
J9181	$14.03	$7.80	$6,688,786	$5.60	$9,052,665	$11.36	$2,872,584
J7672	$1.22	$0.31	$11,560,517	$0.26	$12,175,863	$0.40	$10,400,217
J9293	$206.69	$127.49	$6,846,261	$123.23	$7,214,694	$132.01	$6,456,006
J9185	$173.03	$149.08	$1,890,949	$145.25	$2,193,648	$152.00	$1,660,634
J9010	$204.21	$64.86	$9,942,878	$52.00	$10,860,640	$73.50	$9,326,551
J3370	$10.07	$3.69	$7,235,171	$2.02	$9,122,193	$6.99	$3,491,965
TOTAL			$445,001,565		$498,297,745		$368,075,629

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1996

HCPCS Code	Average Medicare Allowed Amount	Actual Average Wholesale Price	Savings Based on Actual Average Wholesale Price	Lowest Wholesale Price Found	Savings Based on Lowest Wholesale Price	Highest Wholesale Price Found	Savings Based on Highest Wholesale Price
J9217	$499.72	$414.73	$104,365,435	$409.27	$111,066,902	$421.00	$96,663,201
J7620	$0.41	$0.19	$92,199,355	$0.16	$105,604,026	$0.25	$67,530,255
J9265	$181.32	$148.56	$22,757,465	$140.26	$28,526,148	$155.43	$17,986,896
J9202	$378.29	$329.43	$11,215,983	$317.00	$14,067,894	$341.85	$8,364,073
J0640	$21.70	$2.81	$52,514,021	$2.39	$53,670,253	$3.45	$50,724,087
J9045	$82.76	$67.64	$12,539,724	$64.90	$14,814,584	$70.55	$10,128,000
J1440	$154.65	$123.39	$11,592,740	$121.56	$12,271,393	$126.00	$10,624,824
Q0136	$11.93	$10.37	$10,399,198	$9.31	$17,440,772	$10.70	$8,195,663
J2405	$6.08	$4.28	$14,319,348	$3.92	$17,172,050	$4.73	$10,776,959
J1625	$170.02	$125.71	$13,399,842	$122.90	$14,250,690	$128.00	$12,708,277
J1561	$42.21	$16.65	$24,808,622	$12.50	$28,833,317	$34.00	$7,967,739
J7670	$1.23	$0.41	$9,935,367	$0.32	$10,965,079	$0.51	$8,658,040
J1441	$246.34	$196.76	$8,470,488	$191.99	$9,285,542	$202.25	$7,532,512
J9182	$137.57	$70.91	$13,362,365	$37.06	$20,147,028	$112.57	$5,011,200
J9000	$44.19	$13.65	$12,480,751	$10.87	$13,616,851	$17.95	$10,723,475
J9031	$157.53	$133.13	$2,682,097	$112.00	$5,004,749	$148.95	$943,131
J9181	$14.14	$8.02	$5,909,155	$3.71	$10,077,601	$11.26	$2,784,899
J7672	$1.23	$0.44	$4,805,175	$0.32	$5,492,908	$0.55	$4,117,563
J9293	$172.81	$142.40	$2,712,650	$139.91	$2,935,141	$145.38	$2,447,586
J9185	$179.45	$156.50	$2,049,320	$152.00	$2,451,148	$161.00	$1,647,493
J9010	$207.12	$65.46	$10,513,722	$54.00	$11,364,260	$76.00	$9,731,464
J3370	$9.44	$4.42	$4,213,709	$3.45	$5,027,227	$6.45	$2,509,417
TOTAL			$447,246,532		$514,085,563		$357,776,754

APPENDIX C

INDIVIDUAL DRUG ALLOWANCES AND SAVINGS PERCENTAGES FOR 1995 AND 1996

Estimated Medicare Savings if Acquisition Costs Were Used for 1995 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1995 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$455,238,461	$83,728,802	18%
J7620	Albuterol Sulfate 0.083%	$166,901,971	$106,352,439	64%
J9265	Paclitaxel	$79,672,417	$14,425,220	18%
J9202	Goserelin Acetate Implant	$65,806,263	$11,716,412	18%
J0640	Leucovorin Calcium	$64,687,013	$61,175,769	95%
J9045	Carboplatin	$49,306,732	$7,226,520	15%
J1440	Filgrastim, per 300 mcg.	$47,401,344	$8,620,001	18%
Q0136	Epoetin Alpha (Non-ESRD Use)	$47,324,218	$7,942,246	17%
J2405	Ondansetron Hydrochloride	$45,279,311	$10,591,319	23%
J1625	Granisetron Hydrochloride	$33,013,314	$9,709,625	29%
J1561	Immune Globulin	$31,646,866	$23,339,871	74%
J7670	Metaproterenol Sulfate 0.4%	$30,822,456	$23,986,743	78%
J1441	Filgrastim, per 480 mcg.	$29,865,814	$5,256,151	18%
J9182	Etoposide, 100 mg.	$25,713,304	$11,660,930	45%
J9000	Doxorubicin HCL, 10 mg.	$16,017,009	$11,445,719	71%
J9031	BCG (Intravesical)	$15,494,267	$3,659,236	24%
J9181	Etoposide, 10 mg.	$14,510,938	$6,688,786	46%
J7672	Metaproterenol Sulfate 0.6%	$13,876,217	$11,560,517	83%
J9293	Mitoxantrone Hydrochloride	$13,271,172	$6,846,261	52%
J9185	Fludarabine Phosphate	$12,725,400	$1,890,949	15%
J9010	Doxorubicin HCL, 50 mg.	$12,515,401	$9,942,878	79%
J3370	Vancomycin HCL	$12,051,885	$7,235,171	60%
TOTAL		$1,283,141,773	$445,001,565	35%

Estimated Medicare Savings if Acquisition Costs Were Used for 1996 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1996 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$577,547,780	$104,365,435	18%
J7620	Albuterol Sulfate 0.083%	$175,399,846	$92,199,355	53%
J9265	Paclitaxel	$125,093,980	$22,757,465	18%
J9202	Goserelin Acetate Implant	$84,187,487	$11,215,983	13%
J0640	Leucovorin Calcium	$57,323,221	$52,514,021	92%
J9045	Carboplatin	$67,530,797	$12,539,724	19%
J1440	Filgrastim, per 300 mcg.	$54,460,250	$11,592,740	21%
Q0136	Epoetin Alpha (Non-ESRD Use)	$79,558,670	$10,399,198	13%
J2405	Ondansetron Hydrochloride	$47,331,513	$14,319,348	30%
J1625	Granisetron Hydrochloride	$49,691,403	$13,399,842	27%
J1561	Immune Globulin	$35,104,622	$24,808,622	71%
J7670	Metaproterenol Sulfate 0.4%	$14,203,070	$9,935,367	70%
J1441	Filgrastim, per 480 mcg.	$40,592,257	$8,470,488	21%
J9182	Etoposide, 100 mg.	$25,739,111	$13,362,365	52%
J9000	Doxorubicin HCL, 10 mg.	$17,410,833	$12,480,751	72%
J9031	BCG (Intravesical)	$16,544,398	$2,682,097	16%
J9181	Etoposide, 10 mg.	$13,381,243	$5,909,155	44%
J7672	Metaproterenol Sulfate 0.6%	$6,595,854	$4,805,175	73%
J9293	Mitoxantrone Hydrochloride	$14,522,607	$2,712,650	19%
J9185	Fludarabine Phosphate	$15,462,970	$2,049,320	13%
J9010	Doxorubicin HCL, 50 mg.	$14,541,250	$10,513,722	72%
J3370	Vancomycin HCL	$8,234,140	$4,213,709	51%
TOTAL		$1,540,457,302	$447,246,532	29%

APPENDIX D

HEALTH CARE FINANCING ADMINISTRATION COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: OCT - 1 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Excessive Medicare Payments for Prescription Drugs," (OEI-03-97-00290)

We reviewed the above-referenced report that examines Medicare payments for prescription drugs. Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter drugs or many prescription drugs that are self-administered. However, the program will pay for certain categories of drugs used by its beneficiaries. Contracted carriers determine the amounts that Medicare will pay for the drugs based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. OIG findings indicate that at present, it is the AWP that carriers use to develop Medicare reimbursement for prescription drugs. The AWP is reported in The Red Book and other pricing publications and databases used by the pharmaceutical industry. The EAC is determined based on surveys of the actual invoice prices paid for the drug.

The findings contained in the report indicate that Medicare is making excessive payments for prescription drugs. The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs.

OIG suggests that the Health Care Financing Administration (HCFA): (1) reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments; and (2) require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.

HCFA concurs with OIG's recommendations. Our detailed comments are as follows:

OIG Recommendation 1

HCFA should require all carriers to reimburse a uniform allowed amount for each HCPCS drug code.

HCFA Response

We concur. HCFA agrees with OIG's findings and recommendations contained in this report. HCFA convened a workgroup to develop an electronic file consisting of the AWPs for drugs covered by Medicare. HCFA will then distribute this file to Medicare contractors for their use in paying claims for drugs.

OIG Recommendation 2

HCFA should reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.

HCFA Response

We concur. We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.